K102323

510(k) Summary
(21 CFR Part 807.92)

A. Submitter Information

DEC 16 2010

Submitter's Name:	Theken Spine, LLC
Address:	1800 Triplett Blvd. Akron, Ohio 44306
Telephone Number:	330-475-8600
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Contact Person:	Dale Davison
Date Prepared:	08/16/2010

B. Device Information

Trade Name:	Cervical Standalone Intervertebral Body Fusion Device
Common Name:	Cervical Standalone Intervertebral Body Fusion Device
Classification Name:	Spinal Intervertebral Body Fusion Device (per 21 CFR 888.3080)
Device Classification:	Class II (per 21 CFR 888.3080) Panel: Orthopedic, Product Code: ODP
Predicate Device:	Medtronic Sofamor Danek, PEEK PREVAIL™ Cervical Interbody Device (K073285) Globus Medical Inc. COALITION™ Spacer Intervertebral Body Fusion Device (K083389)
Material Composition:	Polyetheretherketone (PEEK-OPTIMA LT) per ASTM F-2026 Tantalum per ASTM F-560, and Titanium 6Al-4V ELI per ASTM F-136
Subject Device Description:	The Cervical Standalone Intervertebral Body Fusion Device is comprised of PEEK-OPTIMA® LT cages which are available in a variety of sizes. The cages include toothed spikes on the top and bottom surfaces to engage with the superior and inferior end plates of neighboring vertebral bodies to resist rotation and migration. The cage shape and open center allow for bony in-growth in and around the implant. A single cage is sufficient to be used at each intervertebral level. Screws are inserted through the anterior titanium face and screwed into the vertebral bodies for bony fixation.
Intended Use:	The Cervical Standalone Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Cervical Standalone Intervertebral Body Fusion Device implants are to be used with autogenous bone graft and implanted via an anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Cervical Standalone Intervertebral Body Fusion Device is to be used with two titanium alloy screws which accompany the implant.

Technological Characteristics:	The technological characteristics of the Cervical Standalone Intervertebral Body Fusion Device are equivalent to the predicate device COALITION™ Spacer Intervertebral Body Fusion Device (K083389) manufactured by Globus Medical Inc. These technological characteristics include the same indications for use, design concepts, feature comparisons, and known biocompatible materials.
Summary of test data:	Mechanical testing of the subject device consisted of static compression, static compression shear, static torsion, static load induced subsidence, static expulsion, dynamic compression, dynamic compression shear and dynamic torsion. All testing was conducted per ASTM F-2077 and ASTM F-2267 guidelines and the device performed as designed and met or exceeded all product specifications. In addition, wear testing was performed in order to determine the characteristics of any particulate wear debris generated during the tests. The result from the wear testing was found to be substantially equivalent to legally marketed devices.

C. Substantial Equivalence

Theken Spine believes that sufficient evidence exists to reasonably conclude that the Cervical Standalone Intervertebral Body Fusion Device is substantially equivalent to the predicate device COALITION™ Spacer Intervertebral Body Fusion Device (K083389) manufactured by Globus Medical Inc. This is based on the design concept, the use of established, known materials, feature comparisons, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis. All implants represent a basic design concept in terms of safety and effectiveness, and differ only in minor details.

Substantial equivalence include:

- The same Indications for use
- The same basic design
- The same operating principle
- The same materials
- The same manufacturing environment
- The same sterilization process
- The same packaging configurations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Theken Spine, LLC
% Mr. Dale Davison
1800 Triplett Boulevard
Akron, OH 44306

SEP

Re: K102323
Trade/Device Name: Cervical Standalone Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: November 12, 2010
Received: November 15, 2010

Dear Mr. Davison:

This letter corrects our substantially equivalent letter of December 16, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102323

DEC 16 2010

Device Name: Cervical Standalone Intervertebral Body Fusion Device

Indications For Use:

The Cervical Standalone Intervertebral Body Fusion Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Cervical Standalone Intervertebral Body Fusion Device implants are to be used with autogenous bone graft and implanted via an anterior approach. The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Cervical Standalone Intervertebral Body Fusion Device is to be used with two titanium alloy screws which accompany the implant.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102323